2d 1746, 1748 (Fed. Cir. 1991). This clearly applies to the present case contrary to the Patent Office's position.

In this regard, the Patent Office explicitly relies on a secondary reference, namely *Zander*, in support of each of the anticipation rejections. Moreover, the Patent Office rejects the same claims in view of the same references in separate obviousness rejections. This clearly suggests that the Patent Office intended to reject Claims 1, 2 and 4-10 under 35 U.S.C. § 103 and not § 102.

Even assuming that the Patent Office can rely on *Zander*, which it cannot, Applicants respectfully submit that the cited references fail to disclose a number of features of the claimed invention. For example, nowhere does the cited art disclose a peritoneal dialysis solution that combines a specified bicarbonate and weak acid concentration in addition to a specific carbon dioxide partial pressure effective in maintaining an acid-base balance in dialysis patients as required by the claimed invention. Indeed, *Schambye* and *Veech I* each at least fail to disclose the carbon dioxide partial pressure features of the claimed invention as even admitted by the Patent Office.

Further, the claimed invention is not inherent in view of the cited art. Of course, "inherency . . . may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Oelrich*, 212 USPQ 323, 326 (CCPA 1981) (quoting *Hansgirg v. Kemmer*, 40 USPQ 665, 667 (CCPA 1939). Again, *Schambye* or *Veech* fail to even disclose the claimed carbon dioxide partial pressure features, let alone in combination with the claimed bicarbonate and weak acid features, as previously discussed.

Moreover, *Zander* cannot be relied on to demonstrate that the claimed features are inherent in view of *Schambye* or *Veech I.* Indeed, *Zander* effectively teaches away from the peritoneal dialysis solutions as required by the claimed invention. For example, while *Zander* may disclose a carbon dioxide partial pressure of 40 mmHg, this solution lacks a weak acid component, thus rendering it deficient in terms of neutralizing hydrogen ions generated endogenously by the dialysis patient as a result of protein metabolism.

Further, *Zander* discloses a solution that combines bicarbonate and acetate at a concentration of 27.2 mmole/l. This acetate concentration (e.g. weak acid concentration) is too high to be effective for maintaining the acid-base balance. Applicants' position is supported by

the Declaration of Dr. Leo Martis that was previously submitted as Exhibit B attached to Applicants' Amendment filed on April 30, 2002. See, *Martis* Declaration, ¶¶ 4 and 5. In view of same, Applicants believe that one skilled in the art would consider the peritoneal dialysis solutions of the claimed invention distinguishable from the cited art. Therefore, Applicants believe that the anticipation rejections are clearly erroneous in law and in fact.

Accordingly, Applicants respectfully request that the anticipation rejections be withdrawn.

In the Office Action, Claims 1-16 are rejected under 35 U.S.C. § 103. More specifically, Claims 1-10 are rejected as allegedly obvious in view of *Schambye* and *Zander*; Claims 1-16 are rejected as allegedly obvious in view of *Veech I* and *Zander*; and Claims 1-16 are rejected as allegedly obvious in view of U.S. Patent No. 6,020,007 ("*Veech II*") and *Zander*. The Patent Office primarily relies on *Schambye*, *Veech I*, and *Veech II* in support of the obviousness rejections and thus relies on *Zander* to remedy the deficiencies of these references.

Applicants respectfully submit that the obviousness rejections are clearly improper. Of the pending claims, Claims 1, 6, 10 and 11 are the sole independent claims. As set forth in independent Claim 1, the peritoneal dialysis solution of the present invention includes a bicarbonate concentration of less than or equal to 30 mM/L, a carbon dioxide partial pressure that is less than 60 mmHg and at least one weak acid at a concentration between 15 mEq/L and approximately 20 mEq/L which is selected from the group consisting of lactate, pyruvate, citrate, isocitrate, cis-aconitase, α-ketoglutarate, succinate, fumarate, malate and oxaloacetate. Acetate is not one of the weak acids which is used in the solution of the present invention.

Claims 6 and 10 require the peritoneal dialysis solution to include dextrose, sodium, chloride, calcium, magnesium, bicarbonate in a range from 20.0 to 30.0 mEq/L and a weak acid in a concentration from 10 to 20 mEq/L that is chosen from the group consisting of lactate, pyruvate, citrate, isocitrate, cis-aconitaase, α-ketoglutarate, succinate, fumarate, malate and oxaloacetate. The solution of Claim 6 also has a carbon dioxide partial pressure that is less than 60 mmHg. The solution of Claim 10 has a carbon dioxide partial pressure that is similar to the partial pressure of a normal subject's blood and further has a pH of 7.0 to 7.4.

The method of Claim 11 includes the step of administering to the patient a peritoneal dialysis solution that has a bicarbonate level and a carbon dioxide partial pressure that is substantially similar to that found in the patient's blood and which further includes dextrose,

sodium, chloride, calcium, magnesium, bicarbonate in a concentration ranging from 20 to 30 mEq/L and a weak acid in a concentration ranging from 10 to 20 mEq/L.

The present invention provides peritoneal dialysis solutions that are biochemically balanced to correct metabolic acidosis associated with chronic renal failure in a more physiological manner. The peritoneal dialysis solution of the present invention has a physiological pH and contains bicarbonate at a concentration that is found in blood involved in diffusive transport of solutes with dialysis fluid. This will block the loss of bicarbonate during peritoneal dialysis, which is the case with known solutions. Additionally, the solution contains carbon dioxide at a partial pressure that is similar to a partial pressure of carbon dioxide found in the blood capillaries. The peritoneal dialysis solution also contains a weak acid at a specified amount needed to neutralize acid generated from endogenus metabolism. These weak acids are also the normal biochemical intermediates of glucose metabolism resulting in neutral end products. See, Specification, page 4, lines 7-24.

In contrast, the primary references, namely, *Schambye*, *Veech I*, and *Veech II* fail to disclose or suggest a number of features of the claimed invention. At a minimum, nowhere do these references disclose or suggest the carbon dioxide partial pressure features, let alone the carbon dioxide partial pressure features combined with the additional other features, such as the unique combination of two buffers(bicarbonate and a weak acid), to provide a biochemically balanced peritoneal dialysis solution capable of correcting metabolic acidosis as required by the claimed invention. Indeed, the Patent Office even admits that these references fail to disclose the carbon dioxide partial pressure features of the claimed invention. Therefore, Applicants believe that the primary references are clearly deficient with respect to the peritoneal dialysis solutions as required by the claimed invention.

Even if combinable, Applicants do not believe that the Patent Office can rely on *Zander* to remedy the deficiencies of the claimed invention. As previously discussed, Applicants believe that *Zander* effectively teaches away from the claimed invention. Indeed, the specific composition in *Zander* as disclosed in column 2 is without a weak acid component. Further, the composition disclosed in column 6 of *Zander* requires a weak acid concentration in the form of acetate that is too high and dangerous to use. Again, this position is supported by the Declaration of Dr. Leo Martis as discussed above.

What the Patent Office clearly has done is to apply hindsight reasoning to justify the obviousness rejections. Of course, this is not proper. Indeed, the present invention provides a unique combination of two buffers (bicarbonate and a weak acid, such as selected from a group that does not include acetic acid) in combination with a specified level of carbon dioxide partial pressure which is both safe and effective in maintaining an acid-base balance in peritoneal dialysis patients. The safety and the efficacy of the solution of the present invention is established by the data presented in the Declaration of Dr. Martis. See, *Martis* Declaration, ¶¶ 7-10. Again, the cited art is clearly deficient with respect to the claimed solutions that require specified levels of bicarbonate, weak acid and carbon dioxide partial pressure to maintain an acid-base balance. In view of same, Applicants believe that one skilled in the art would not be inclined to modify the cited art to arrive at the claimed invention.

Based on at least the above-noted reasons, Applicants believe that the cited art fails to disclose or suggest the claimed invention. Therefore, Applicants respectfully submit that the cited art, even if combinable, fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request that the obviousness rejections be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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